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Nos. 95-754 and 95-886

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR and MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF THE AMERICAN INSURANCE ASSOCIATION, THE AMERICAN TORT REFORM ASSOCIATION, AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Of Counsel

JAMES LAWSON KIMBLE
AMERICAN INSURANCE ASSOCIATION
1130 Connecticut Avenue, N.W.
Suite 1000
Washington, D.C. 20036
(202) 828-7174

SHERMAN JOYCE
AMERICAN TORT REFORM ASSOCIATION
1212 New York Avenue, N.W.
Suite 515
Washington, D.C. 20005
(202) 682-1163

JAN S. AMUNDSON
NATIONAL ASSOCIATION OF MANUFACTURERS
1331 Pennsylvania Avenue, N.W.
Suite 1500
Washington, D.C. 20004
(202) 637-3055

VICTOR E. SCHWARTZ *
JOSEPH N. ONEK
ROBERT P. CHARROW
MARK A. BEHRENS
MONICA G. PARHAM
CROWELL & MORING
1001 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2595
(202) 624-2500
Attorneys for Amici Curiae

* Counsel of Record

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act preempts state common law claims that would expose a manufacturer to liability for marketing a medical device design that the Food and Drug Administration reviewed and affirmatively authorized for marketing under the Act's complex regulatory scheme.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iv
STATEMENT OF INTEREST	1
INTRODUCTION AND SUMMARY OF ARGUMENT	3
ARGUMENT	5
I. CONGRESS HARMONIZED NATIONAL AND LOCAL INTERESTS BY PROVIDING A RULEMAKING PROCESS TO PERMIT EXEMPTIONS FROM PREEMPTION	5
A. The MDA Permits States To Petition The FDA For Exemptions From Preemption Through The Rulemaking Process	5
B. The Rulemaking Process Applies To State Tort Requirements	9
II. STATE TORT LAW REQUIREMENTS, UNLESS FOUND APPROPRIATE FOR EXEMPTION FROM PREEMPTION BY THE FDA, WOULD UNDERMINE UNIFORMITY AND IMPERIL THE AVAILABILITY AND SAFETY OF MEDICAL DEVICES	13
III. FINDING PREEMPTION IS CONSISTENT WITH CONGRESSIONAL INTENT AND IS GOOD PUBLIC POLICY	17
CONCLUSION	20

TABLE OF AUTHORITIES

CASES Page

Artiglio v. Superior Court (McGhan Medical Corp.), 22 Cal. App. 4th 1388, 27 Cal. Rptr. 2d 589 (1994) 14
Berger v. Personal Prods., Inc., 797 P.2d 1148 (Wash. 1990), *cert. denied*, 499 U.S. 961 (1991) .. 10
Bristol-Meyers Co. v. Gonzalez, 561 S.W.2d 801 (Tex. 1978) 14
Brown v. Superior Court (Abbott Laboratories), 751 P.2d 470 (Cal. 1988) 14, 18
Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 9
Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) 15
Duvall v. Bristol-Myers Squibb Co., 65 F.3d 392 (4th Cir. 1995) 3
Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C. Cir.), *cert. denied*, 498 U.S. 950 (1990) 16
English v. Mentor Corp., 67 F.3d 477 (3d Cir. 1995) 3
Flanagan v. State, 625 So. 2d 827 (Fla. 1993) 16
Habecker v. Clark Equip. Co., 36 F.3d 278 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1313 (1995) 16
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TABLE OF AUTHORITIES—Continued

	Page
Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995), *petition for cert. filed* Feb. 20, 1996 (No. 95-1323)	9
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Rubel v. Eli Lilly and Co., 681 F. Supp. 151 (S.D.N.Y. 1987), *recon. denied*, 1995 WL 92303 (Mar. 7, 1995)	10
Schultz v. State, 664 A.2d 60 (Md. 1995)	16
Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995)	4
STATUTES	
21 U.S.C. §§ 301 *et seq.* (1988 & Supp. 1993)	2
21 U.S.C. §§ 351, 352 (1988)	5
21 U.S.C. §§ 360c *et seq.* (1988 & Supp. 1993)	2, 3
21 U.S.C. §§ 360k(a), (b) (1988)	*passim*
28 U.S.C. §§ 1346(b), 2671 *et seq.*	11
Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 26050 *et seq.* (repealed)	6
REGULATIONS	
21 C.F.R. § 807.81(a)(3)(i)	15
21 C.F.R. Part 808, subpart C	7
21 C.F.R. §§ 808.1(b), (c)	13
21 C.F.R. § 808.5	11
21 C.F.R. §§ 808.20(c)(4), (c)(7), (d)	*passim*
LEGISLATIVE HISTORY	
Sen. Rep. No. 33, 94th Cong., 2d Sess. (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070	3, 17
H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976)	*passim*

TABLE OF AUTHORITIES—Continued

Page

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TABLE OF AUTHORITIES—Continued

	Page
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59 Fed. Reg. 26,352-26,353 (1994)	12

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STATEMENT OF INTEREST

Amici represent casualty insurers and manufacturers of health care products.[1] This case is of interest and particular importance to the *amici* because its outcome will likely affect the quality, availability, and cost of health care for every American. In terms of both costs and effectiveness, sophisticated medical devices have become

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[1] Pursuant to Rule 37, letters of consent have been filed with the Clerk of the Court.

a central feature of modern medicine. Congress recognized that rational regulation of complex medical devices requires a considerable degree of national uniformity. The Medical Device Amendments of 1976 ("MDA")[2] to the Federal Food, Drug, and Cosmetic Act of 1938[3] were designed to achieve that uniformity, while preserving tort remedies in appropriate situations approved by the Food and Drug Administration ("FDA") through rulemaking. *See* 21 U.S.C. § 360k(b) (1988).

The American Insurance Association ("AIA") is a national trade organization representing over 270 companies writing casualty/property insurance in every state and jurisdiction of the United States. These companies provide 27 percent of all casualty/property insurance underwritten in the United States. AIA companies are affiliated with 79,000 independent insurance agents nationwide.

The American Tort Reform Association ("ATRA"), founded in 1986, is a broad-based, bipartisan coalition of more than 300 businesses, corporations, municipalities, associations, and professional firms who have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance and predictability in civil litigation.

The National Association of Manufacturers ("NAM") is the nation's oldest and largest broad-based industrial trade association. Its nearly 14,000 member companies and subsidiaries, including approximately 10,000 small manufacturers, are in every state and produce about 85 percent of U.S. manufactured goods. Through its member companies and affiliated associations, the NAM represents every industrial sector and more than 18 million employees, and as such, the Court's ruling in this case could have significant ramifications beyond the subject litigation.

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[2] 21 U.S.C. §§ 360c *et seq.* (1988 & Supp. 1993).

[3] 21 U.S.C. §§ 301 *et seq.* (1988 & Supp. 1993).

INTRODUCTION AND SUMMARY OF ARGUMENT

In the Medical Device Amendments of 1976, Congress sought to avoid conflicting rules,[4] improve safety,[5] encourage innovation,[6] and assure the continued availability of affordable, safe and effective medical devices without denying compensation to injured persons.

Congress implemented its intent through the MDA's general preemption provision, 21 U.S.C. § 360k(a) (1988), and the provision authorizing states to petition the FDA to impose additional requirements. *See* 21 U.S.C. § 360k(b) (1988). These provisions, as enacted, do not imply that state tort law is foreclosed or that individuals who are injured because of defective medical devices are left without a remedy. To the contrary, the MDA specifically authorizes states to adopt tort remedies in medical device cases after the FDA has determined, following rulemaking, that the additional requirements that would be imposed by state tort law neither undermine the safety or effectiveness of the device nor undermine the availability of the device in any state, including the state proposing the new requirement. *See* 21 U.S.C. § 360k(b) (1988).[7]

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[4] *See* Sen. Rep. No. 33, 94th Cong., 2d Sess. 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071. *See also Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1994); *King v. Collagen Corp.*, 983 F.2d 1130, 1137-38 (1st Cir.), *cert. denied*, 114 U.S. 84 (1993).

[5] *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (*1976*); 21 U.S.C. § 360c (1988 and Supp. 1995). *See also Duvall v. Bristol-Myers Squibb Co.*, 65 F.3d 392, 395 (4th Cir. 1995) (citing *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1944)); *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995).

[6] *See generally* National Academy of Sciences, *New Medical Devices: Invention, Development, And Use* 73 (National Academy Press, 1988) (observing that subjecting medical devices to both federal regulation through the FDA and state regulation through state court requirements produces "serious distortions").

[7] In addition, an injured party may receive restitution through the criminal process. The First Circuit Court of Appeals recently

Congress, when it enacted the MDA, pictured a system where national regulation would predominate, and distortions brought about by local regulation would be controlled and minimized.[8] Congress intended to achieve these goals by preempting state and local requirements that could burden interstate commerce by threatening the availability of medical devices.[9]

The preemption and petition provisions of the MDA permit the divergent regimes of federal regulation and state common law to be rationally harmonized. The MDA preserves the ability of injured persons to receive compensation[10] and the need for "uniform, nationwide standards"[11] governing medical devices. Indeed, only

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noted that a court finding noncompliance with FDA requirements may order payment of restitution as part of criminal sanctions against a manufacturer. *See Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 30 (1st Cir. 1995).

[8] Concern that states and local subdivisions would impose their own requirements on sophisticated medical devices was a significant factor in Congress's desire to extend federal preemption. The legislative history of the MDA reveals that:

> The Committee recognizes that if a substantial number of different requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened. For this reason the reported bill prescribes a general rule that no State or political subdivision thereof may establish or continue in effect any requirement with respect to a device for human use which is different from, or in addition to, any requirement made applicable to such device.

H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976).

[9] *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 12, 45 (1976).

[10] *See* 21 U.S.C. § 360k(b) (1988).

[11] *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995). *See also* Sen. Rep. No. 295, 94th Cong., 2d Sess. 1071 (1976) (Congress "wants to be sure that the FDA has the proper authority to regulate the process so that Americans are not put at risk from the use of unsafe and ineffective medical devices"); H.R. Rep. No. 853, 94th Cong., 2d Sess. 15 (1976). *See generally* American Law

through the preemption and petition provisions can these goals be simultaneously achieved.

ARGUMENT

I. CONGRESS HARMONIZED NATIONAL AND LOCAL INTERESTS BY PROVIDING A RULEMAKING PROCESS TO PERMIT EXEMPTIONS FROM PREEMPTION.

A. The MDA Permits States To Petition The FDA For Exemptions From Preemption Through The Rulemaking Process.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938 represent a carefully considered congressional response to the burgeoning area of medical device technology. Prior to the enactment of the MDA, there was no federal premarket review, although there were general federal controls regarding adulterated and misbranded devices.[12] The MDA thus federalized within the FDA what had largely been within the province of individual state regulators, in the

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Institute, 2 *Enterprise Responsibility For Personal Injury—Reporters' Study* 106 (1991) ("Federal statutes providing for nationally uniform product regulation present a strong case for recognizing preemption because of the limited state interest in imposing more stringent standards through state tort law and the potential adverse effect of tort liability on investment, innovation, and international competitiveness.")

[12] The Federal Food, Drug, and Cosmetic Act of 1938 drew a sharp distinction between drugs and medical devices. While devices were subject to the Act's adulteration and misbranding prescriptions, *see* 21 U.S.C. §§ 351, 352 (1988), the Act's premarket review provisions did not apply to devices. The 1976 MDA gave the FDA comprehensive regulatory authority over medical devices for the first time. In 1990, Congress amended the MDA by enacting the Safe Medical Devices Act of 1990 ("SMDA"). The SMDA contained several provisions designed to provide the FDA with greater regulatory authority over devices. *See* H.R. Rep. No. 808, 101st Cong., 2d Sess. 13 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6306.

expectation of improving safety and effectiveness by developing national standards and requirements.[13]

As a necessary corollary to the new concentration of authority within the FDA, Congress expressly preempted all state and local requirements that are "different from, or in addition to, any requirement applicable under [the MDA]." 21 U.S.C. § 360k(a)(1) (1988). Congress also sought to accommodate the diverse needs of individual states, including those expressed through state tort litigation, in a rational manner consistent with the goal of achieving national uniformity in the distribution of medical devices. Congress, therefore, created an "escape valve" from the MDA's expansive express preemption provision which permits states to petition the FDA for leave to adopt their own standards. The "petition provision" of the MDA, 21 U.S.C. § 360k(b) (1988), states:

> Upon application of a State or a political subdivision thereof, the Secretary [of Health and Human Services] may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed by such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> > (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
> >
> > (2) the requirement—
> >
> > > (A) is required by compelling local conditions, and

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[13] Some states, such as California, had long before created a full-fledged food and drug administration to regulate medical devices sold within the state. *See generally* the Sherman Food, Drug, and Cosmetic Law, Cal. Health & Safety Code §§ 26050 *et seq.* The Sherman Food, Drug, and Cosmetic Law has since been repealed.

> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k(b) (1988).

This petition provision rebuts the claim that Congress intended to permit state courts to alter federal labeling, design, or manufacturing requirements for complex medical devices and renders the Lohr's position anomalous. Under 21 U.S.C. § 360k(b), a state which, after months of detailed study and scores of public hearings, determines that a particular requirement is necessary for a medical device marketed within its borders must still proceed to file an application with the FDA authorizing the state to adopt the new requirement. Under the Lohr's reasoning, however, a court can in essence impose the very same requirement without any need to bring the matter to the FDA's attention. There is no basis for believing that Congress intended such a dichotomy between state legislative or administrative requirements and state tort law requirements.

The petition provision has been invoked by numerous states seeking exemption from preemption.[14] The final rule issued by the FDA with respect to the applications of Massachusetts and Rhode Island for preemption exemptions for their state hearing aid requirements is particularly instructive.[15] Initially, the laws of both states required mandatory audiological evaluation prior to purchase of hearing aids. Nevertheless, after receiving extensive comments and "reviewing the conflicting information in the public record," the FDA concluded "that

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[14] *See, e.g.*, 45 Fed. Reg. 67,321 (1980); 45 Fed. Reg. 67,325 (1980) (applications for exemption regarding state hearing aid requirements by twenty states and the District of Columbia). A complete list of exemptions granted to state and local governments is contained at 21 C.F.R. Part 808, subpart C.

[15] *See* 45 Fed. Reg. 67,326 (1980).

audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids."[16] The agency further concluded that the requirement of mandatory audiological evaluation "could increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification."[17]

The formal rulemaking process set forth in the MDA permits the FDA the opportunity, after hearing from experts and all interested parties, to make an informed determination as to whether there should be an exemption from preemption. Through this process, the FDA can balance the need for national uniformity against other legitimate interests in a fair and informed manner.[18] Congress intended this rulemaking process, not the judicial process, to be the primary mechanism for balancing competing interests and determining when exemption from

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[16] 45 Fed. Reg. 67,329 (1980).

[17] 45 Fed. Reg. 67,329 (1980). The final rule issued by the FDA with respect to California's application for a blanket exemption for its own pre-existing medical device requirements (The Sherman Food, Drug, and Cosmetic Act) is also instructive. *See* 45 Fed. Reg. 67,321 (1980). In issuing the final rule, the FDA carefully reviewed California's requirements, held a public hearing, and received extensive comments. Ultimately, the FDA exempted some of California's requirements from preemption and denied exemption to others. Notably, during the course of rulemaking the FDA reversed its position on one proposed exemption based on comments it received, and ultimately concluded that California had not adequately addressed the issue of whether its requirements concerning color additives might unduly burden interstate commerce. 45 Fed. Reg. 67,321 ¶ 10 (1980). *See also* 21 C.F.R. § 808.20(c)(7) (providing that an application for exemption should include information of how public health may be benefitted and how interstate commerce may be affected if an exemption is granted).

[18] Congress understood that rulemaking is ideally suited for balancing competing interests and developing policy that can have widespread effects. *See generally* Stephen G. Breyer & Richard B. Stewart, *Administrative Law and Regulatory Policy* 472 (2d ed. 1985).

federal labeling, design, or manufacturing requirements for complex medical devices is appropriate.[19]

B. The Rulemaking Process Applies To State Tort Requirements.

Congress also intended the MDA's rulemaking process to apply to state court requirements. This interpretation is fully consistent with this Court's holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), which correctly made clear that state tort judgments can constitute "requirements" within the meaning of a federal preemption statute.[20] Following *Cipollone*, courts interpreting the MDA have held that "21 U.S.C. § 360k(a)'s preemption of state 'requirement[s]' 'different from, or in addition to' those of the MDA is broad enough to include state common law causes of action."[21]

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[19] There is judicial review of MDA rulemaking. *See, e.g., Massachusetts v. Hayes*, 691 F.2d 57 (1st Cir. 1982). *See generally* Paul Hyman, *Litigated Cases under the Medical Device Amendments of 1976*, 40 Food Drug Cosm. L.J. 85 (1986).

[20] *See id.* at 521 (plurality op. of Stevens, J., Rehnquist, C.J., and White and O'Connor, J.J. ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations in the form of common law rules.") *See also id.* at 547-48 (Scalia, J., joined by Thomas J., concurring in the judgment in part and dissenting in part).

[21] *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1275 (7th Cir. 1995), *petition for cert. filed* Feb. 20, 1996 (No. 95-1323). *See also* Victor E. Schwartz, Robert P. Charrow & Mark A. Behrens, *Following the Supreme Court's Analysis in Cipollone, Courts Are Finding Broad Preemption in Sophisticated Medical Device Tort Litigation*, 17 J. Prods. & Toxics Liab. 31 (1995). The view that Congress intended the preemption provision to apply to court decisions finds support in the fact that Congress chose not to revisit the express preemption provision of the MDA when it enacted the 1990 SMDA, despite the fact that *every* reported decision to address the issue of preemption of state tort law failure to warn claims held the MDA to be preemptive. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, *reh'g denied*, 873 F.2d 297

Thus, for example, a lawsuit based on an allegedly inadequate design or warning system, (*e.g.*, there was a light but not a bell or whistle) could impose an additional design or labeling requirement on a device whose design or labeling has been approved or cleared by the FDA.[22] It is therefore preempted, absent a successful exemption petition by the state, just as a state statute which requires particular warning language or a particular warning system would be preempted.

The rulemaking process mandated by Congress to exempt state court "requirements" from the MDA's pre-

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(5th Cir. 1989); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475 (S.D. Ind. 1988); *Berger v. Personal Prods., Inc.*, 797 P.2d 1148 (Wash. 1990), *cert. denied*, 499 U.S. 961 (1991).

[22] It should be noted that in many jurisdictions—including Arizona, Colorado, Connecticut, the District of Columbia, Delaware, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Missouri, New Mexico, New York, North Carolina, Pennsylvania, South Carolina, Utah and Wisconsin—a judgment in a single case can be given statewide effect through the application of offensive collateral estoppel principles. By invoking the doctrine, a plaintiff who was not a party to a prior action can seek to establish a claim against a party who had been a party to the prior action. In so doing ,a defendant may be barred from asserting a defense that the defendant has previously litigated and lost against a different plaintiff. *See Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 331 (1979). Notably, trial courts in these jurisdictions have wide discretion over whether the use of offensive collateral estoppel is appropriate in a particular case. *See id.*

The impact of offensive assertions of collateral estoppel has been dramatic in the pharmaceutical area. For example, in *Rubel v. Eli Lilly and Co.*, 681 F. Supp. 151 (S.D.N.Y. 1987), *recon. denied*, 1995 WL 92303 (Mar. 7, 1995), the court held that prior verdicts in cases involving diethylstilbestrol ("DES") manufacturer Eli Lilly were not so inconsistent as to preclude use of offensive collateral estoppel to bar manufacturer from relitigating issue of negligent testing. Through the ripple effects created through offensive collateral estoppel, this single judgment potentially had an impact far beyond the four corners of the case, despite subsequent decisions precluding use of offensive collateral estoppel on related—and arguably identical—issues.

emptive effect accommodates state tort law litigation.[23] States are likely to file petitions where requested to do so by injured state citizens.[24] Moreover, the state's application for an exemption need not be limited to a single case. The state can petition to impose a new requirement, *e.g.*, clearer warning language or stronger design features, for a class or classes of devices.[25] Just as with a statutory requirement, the state would have to provide information demonstrating that the judicially imposed requirement would be more stringent than the FDA's requirement or, alternatively, if the requirement is needed due to compelling local conditions, that compliance with the requirement would not cause the device to be in violation of any applicable requirement under the Act. *See* 21 C.F.R. § 808.20(c)(4). In addition, the state would have to provide information "on how the public health may be benefitted and how interstate commerce

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[23] The "escape valve" from preemption that Congress created in the MDA is somewhat analogous to another congressional statute addressing liability law: the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 1346(b), 2671 *et seq.* (1995). Before Congress enacted the FTCA, the federal government was immune from civil tort suits. *See* W. Page Keeton, *Prosser and Keeton on the Law of Torts* § 131 (5th ed. 1984). Congress enacted the FTCA to allow recovery against the United States for certain types of conduct, but it was careful to impose strong procedures to protect the government from runaway liability. For example, FTCA cases are decided by a federal judge, not a jury, punitive damages are not available, the plaintiff's attorney's contingent fee is subject to express regulation (below the general "market rate") and prior to filing suit, the plaintiff must exhaust administrative remedies.

[24] FDA regulations expressly provide for an advisory opinion. *See* 21 C.F.R. § 808.5. They also provide that a state can request expedited consideration of its exemption application if "litigation regarding applicabilty of the requirement is pending." 21 C.F.R. § 808.20(d).

[25] Page 24 of the Lohr's brief misconstrues 21 U.S.C. § 360k(b) (1988) when it suggests that states would have to petition the FDA for exemptions for individual plaintiffs on a case-by-case basis. Nothing in the statute requires such a procedure.

may be affected, if an exemption is granted." 21 C.F.R. § 808.20(c)(7).

The FDA, after a hearing and a comment period, would first determine whether the proposed new requirement met one of the two statutory bases for exemption. If it did, the FDA still would have discretion to deny the exemption. *See, e.g., Massachusetts v. Hayes*, 691 F.2d 57, 60 (1st Cir. 1982).[26] It could choose to evaluate all the relevant factors bearing on the public health, including whether the requirement enhances the safety and effectiveness of the device,[27] and whether the requirement is so costly that it is likely to reduce the availability of the device.[28] Congress appropriately decided that such evaluation is better done by the FDA through its rulemaking process than by courts and lay juries through the judicial process.

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[26] The plain lannguage of 21 U.S.C. § 360k(b) (1988) emphasizes the discretion vested in the FDA, providing that "Upon application of a State . . . the Secretary *may* . . . exempt [from preemption]" (emphasis supplied).

[27] *See* 45 Fed. Reg. 67,321 (1980), where the FDA, in considering a state's exemption application for hearing aids, refused to approve an exemption for an existing state requirement after finding that "an audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids."

[28] *See* 43 Fed. Reg. 18661, 18664 (1978) ("[T]he Commissioner [of Food and Drugs] may not grant an exemption if he determines that the granting of an exemption would not be in the best interest of the public health, taking into account the potential effect on the public health of granting or denying an exemption, *e.g.*, additional cost to consumer, availability of needed products, etc.") The cost to manufacturers and end users of new regulatory requirements and its impact on availability have always been key factors in FDA decision-making. *See* 59 Fed. Reg. 26,352-26,353 (1994) (in establishing new standards for electrode leads, the FDA solicited comments on the "[c]ost to manufacturers and the user community to convert to protected electrode lead wires").

II. STATE TORT LAW REQUIREMENTS, UNLESS FOUND APPROPRIATE FOR EXEMPTION FROM PREEMPTION BY THE FDA, WOULD UNDERMINE UNIFORMITY AND IMPERIL THE AVAILABILITY AND SAFETY OF MEDICAL DEVICES.

Sophisticated medical devices differ from ordinary consumer goods: they are complex and frequently incorporate "cutting-edge" technologies; they are generally prescribed for use by physicians; and they offer substantial (and unique) benefits and involve inherent risks. As a result, Congress sought to, and in fact did, impose nationally uniform standards on medical devices which were intended to supplant the diverse, conflicting and often ineffectual procedures and requirements that various "states [had] established" for regulating devices. H.R. Rep. 853, 94th Cong., 2d Sess. 45 (1976). Congress expressly "recognize[d] that if a substantial number of differing requirements applicable to medical devices are imposed by jurisdictions other than the federal government, interstate commerce would be unduly burdened." *Id.* Congress also recognized that responsibility for developing these national standards should be left to trained professionals, *e.g.*, scientists, physicians and engineers, and understood that excessive, inappropriate, and erratic regulation would stifle innovation, jeopardize the availability of medical devices, and substantially increase health care costs.[20] The preemption and exemption provisions of the MDA were designed to ensure that any form of state requirement—whether by "statute, ordinance, regulation, or court decision," 21 C.F.R. § 808.1 (b)—would not undermine these goals.

Nowhere is the potential for undermining Congress's intent as great as where medical device requirements are

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[20] *See* H.R. Rep. 853, 94th Cong., 2d Sess. 12 (1976) ("The Committee has developed a balanced regulatory proposal intended to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions.")

set through state "tort regulation." Tort laws vary widely from state to state, and sometimes within states.[30] Indeed, state laws differ on even some of the most basic principles of product liability law.[31]

For example, in some states such as California, FDA premarket approval or clearance insulates a device manufacturer from a strict liability design defect claim.[32] In other states, such as Texas, however, FDA approval or clearance has little bearing on claims alleging strict products liability.[33] Thus, a jury in Texas, but not California,

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[30] The variation in law from state to state increases uncertainty and costs without providing a corresponding benefit in the form of improved health or safety. *See generally* Jason Scott Johnson, *Uncertainty Chaos, and the Torts Process; An Economic Analysis of Legal Form*, 76 Cornell L. Rev. 341 (1991).

[31] *See Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1300 (7th Cir.) (Posner, J.), *cert. denied sub nom. Grady v. Rhone-Poulenc Rorer, Inc.*, 116 S. Ct. 184 (1995). *See generally* John Wade *et al., Prosser, Wade and Schwartz's Cases and Materials on Torts* 740 (9th ed. 1994) (describing various standards used by states to determine whether a product is "defective."); Victor E. Schwartz, *Comparative Negligence* app. b (3d ed. 1994) (setting forth diverse approaches taken by the states to address the issue of plaintiff fault and its effect on a defendant's liability).

[32] *See Artiglio v. Superior Court (McGhan Medical Corp.)*, 22 Cal. App. 4th 1388, 27 Cal. Rptr. 2d 589 (1994) (silicone gel breast implants); *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 13 Cal. Rptr. 2d 811 (1992) (IUDs) and *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 5 Cal. Rptr. 2d 377 (1992) (penile prostheses), *opinion modified* (Mar. 17, 1992). The policy engine driving these cases, which was first set forth in *Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470, 479 (Cal. 1988), is that medical devices, like pharmaceuticals, are incapable of being made absolutely safe, but are so important and beneficial to society that liability law should not be permitted to discourage their innovation or distribution.

[33] *See Bristol-Meyers Co. v. Gonzalez*, 561 S.W.2d 801 (Tex. 1978) (affirming finding that warning as to drug's dangers was not adequate, as a matter of law, simply because it complied with FDA labeling requirements, and upholding six figure verdict based on inadequate warning). Unfortunately, in most jurisdictions, courts

might hold a manufacturer of a lifesaving device strictly liable for an allegedly inadequate design, obligating the manufacturer to change the device's design or doom itself to certain, repeated damages awards, including punitive damages. Ironically, the redesigned device could *not* be sold without prior FDA clearance or approval.[34] Until the lengthy FDA clearance or approval process is completed, the lifesaving device would not be available to persons in need.

In addition to the substantive tort law, the pertinent rules of evidence also vary widely from state to state. These differences are particularly troublesome where a court or jury is asked to render a scientific or technical judgment.[35] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2795 (1993), this Court sought to ensure that federal courts would be guided only by scientific and technical evidence that had been "derived by the scientific method." While many states have em-

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may find that a medical device's design is defective, its warning inadequate, or its labeling incomplete even if the FDA has mandated the precise language and has determined that the product is safe and effective. *See* Restatement (Third) of the law of Torts: Products Liability § 7(b) (Tent. Draft No. 2, Mar. 13, 1995); *Merrell Dow Pharmaceuticals, Inc. v. Oxendine*, 649 A.2d 825, 829 (D.C.App. 1994) (FDA finding that drug is "safe and effective," ". . . is a term of art, not a legal conclusion for state tort law purposes").

[34] Once the FDA determines that a device is "substantially equivalent" and clears the device for marketing, the manufacturer cannot change the device design or construction in a manner "that could significantly affect the safety or effectiveness of the device" without an additional 510(k) review by the FDA. *See* 21 C.F.R. § 807.81(a)(3)(i).

[35] Concern over the ability of lay factfinders fully to comprehend complex scientific principles is not new. *See* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 Harv. L. Rev. 40, 54 (1902) (noting paradox in asking jurors to judge which of two expert statements is true, when the experts are called precisely because the jury is incompetent in that area).

braced *Daubert*, others have declined.[36] As a result, decisions about the design, labeling, or manufacture of complicated medical devices may be influenced by aberrant opinions not derived in accordance with the scientific method.[37]

Furthermore, regulation by state tort law, without exemption by the FDA through the formal rulemaking process, guarantees that requirements for complex technologies, which are often understood only by experienced and knowledgeable experts, will be shaped by well-intended lay jurors or judges who may lack the foundation necessary to balance the competing concerns which are involved in developing policy decisions affecting the national health. Scrutiny of federal labeling, design, or manufacturing requirements for complex medical devices by courts and lay persons would also be inconsistent with the Congress's and the FDA's tradition of relying

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[36] *See, e.g., Schultz v. State*, 664 A.2d 60, 64 (Md. 1995) (test based on *Frye* standard is still "the standard utilized in Maryland"); *People v. Leahy*, 882 P.2d 321, 323 (Cal. 1994) (California court refused to substantively revise pre-*Daubert* test); *Flanagan v. State*, 625 So. 2d 827, 829 n.2 (Fla. 1993) ("Florida continues to adhere to the *Frye* test for the admissibility of scientific opinions"). Some federal courts have even refused to apply the Federal Rules of Evidence in diversity cases if those rules would undermine a state's substantive law. *See, e.g., Habecker v. Clark Equip. Co.*, 36 F.3d 278 (3d Cir. 1994), *cert. denied*, 115 S. Ct. 1313 (1995).

[37] *See, e.g., Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159 (D.C. Cir.) (overturning $75 million punitive damages award), *cert. denied*, 498 U.S. 950 (1990); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318 (1986) (imposing punishment against the manufacturer of the Sabin oral polio vaccine, because the company had not used a version of polio vaccine that had been abandoned for general use in the United States for over two decades. The Kansas Supreme Court, by the slimmest of margins, one vote, reversed an $8 million punitive damages verdict. One vote the other way and children in Kansas could have lost access to the Sabin polio vaccine), *aff'd*, 758 P.2d 206 (Kan. 1988).

heavily on expert scientific review before permitting a newly designed medical device to be marketed.[38]

III. FINDING PREEMPTION IS CONSISTENT WITH CONGRESSIONAL INTENT AND IS GOOD PUBLIC POLICY.

Open-ended tort regulation would produce unwanted and socially undesirable state requirements on medical device manufacturers, which would distort Congress's intent.[39] Without question, under the specter of unlimited and unpredictable tort judgments, "manufacturers might be reluctant to undertake research programs to develop certain devices that would prove beneficial or to distribute others that are available to be marketed, because of fear of large adverse monetary judgments."[40] Further, the

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[38] Indeed, Congress focused on the need to tap into "scientific expertise" in regulating medical devises. *See generally* H.R. Rep. No. 853, 94th Cong., 2d Sess. 10-12 (1976); Sen. Rep. No. 33, 94th Cong., 2d Sess. 6-11 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1076-80.

[39] According to a report published by the National Academy of Sciences, the purposes of FDA regulation and tort litigation are remarkably different and indeed often contradictory. *See generally* National Academy of Sciences, *New Medical Devices: Invention, Development, and Use* 73-74 (National Academy Press, 1988). FDA regulation is intended to assure the public health through the continued availability of new, safe, and effective medical products, and thus necessarily involves a balancing of overall risks and benefits. On the other hand, injured parties with product liability lawsuits are not directly concerned with public policy, with the effects of the decision-making on the public at large, or with the impact that a decision will have on the future availability or cost of a product; their primary goal is to seek compensation. *Id.*

[40] Victor E. Schwartz, Robert P. Charrow & Mark A. Behrens, *Following the Supreme Court's Analysis in Cipollone, Courts Are Finding Broad Preemption in Sophisticated Medical Device Tort Litigation*, 17 J. Prods. & Toxics Liab. 31, 44 (1995). *See generally* Steven Garber, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* xxxii (1993) (RAND study recommending compliance with FDA regulations as a complete defense to liability for drugs and sophisticated medical devices on public

additional expense of insuring against such liability—assuming insurance would be available—could place the cost of many beneficial devices beyond the reach of those who need them.[41]

A finding that state tort laws are not subject to the preemption and exemption provisions of the MDA will undermine the availability of medical devices.[42] This is aptly illustrated by recent litigation involving suppliers of raw materials used to manufacture medical devices. These suppliers are not subject to the preemption provision of the MDA; therefore, a look at their situation provides a window into how the future of medical device availability may look in an environment of "no preemption."

Recently, liability concerns have caused suppliers of raw materials and component parts to medical implant manufacturers to cease supplying these critical base materials, jeopardizing the availability of implantable medical devices necessary to the lives of millions of Americans. A 1994 study by Aronoff Associates concluded that there are significant numbers of raw materials that are "at risk" of shortages in the immediate future.[43] Suppliers have found that the risks and costs of responding to litigation

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policy grounds); Peter Huber & Robert Litan, *The Liability Maze: The Impact of Liability Law on Safety and Innovation* 7 (1991) (reporting on American Medical Association study finding that "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance").

[41] *See generally Brown v. Superior Court (Abbott Laboratories)*, 751 P.2d 470, 479 (Cal. 1988).

[42] *See generally* Peter Huber, *Safety And The Second Best: The Hazards Of Public Risk Management In The Courts*, 85 Colum. L. Rev. 277, 337 (1985) ("[I]t is insane to snuff out with legal paper those who would light the candle of a cure. . . . It is out of the nettle, danger, that we pluck the flower, safety").

[43] *See* Aronoff Associates, *Market Study: Biomaterials Supply for Permanent Medical Implants* (Mar. 1994).

related to medical implants far exceeds potential sales revenues, even though courts are not finding suppliers liable.[44]

The biomaterials availability crisis is already having an adverse impact on consumers. Consider the case of Peggy Phillips, a survivor of two episodes of Sudden Death Syndrome and the recipient of an Automatic Implantable Cardioverter Defibrillator device. On April 4, 1995, Ms. Phillips testified before the Consumer Affairs, Foreign Commerce and Tourism Subcommittee of the Senate Committee on Commerce, Science and Transportation that, as a patient with a lifesaving medical implant, her worry is that such devices "may not be available to those who need them," because the "threat of liability suits" is causing suppliers of raw materials to pull out of the medical device market.[45]

Ms. Phillips shared with the Subcommittee her experience on a recent panel discussion sponsored by the American Institute for Medical and Biological Engineering in which representatives of medical science and the device industry put "tort law on trial." A woman in the audience wanted to know if the threatened shortage of biomaterials was serious. "A chill ran up my spine," Ms. Phillips testified, "when the panelists could not guarantee that [the battery used to power my Automatic Implantable Cardioverter Defibrillator device] would be available in the United States because of the threatening shortage of raw materials used in the devices resulting from product liability concerns." [46]

In light of the express congressional purposes in enacting the MDA, regulation by tort verdict—unchecked by

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[44] *See* Edward M. Mansfield, *Reflections on Current Limits on Component and Raw Material Supplier Liability and the Proposed Third Restatement*, 84 Ky. L.J. 221, 235-37 (1995-96).

[45] Sen. Rep. No. 104-69, 104th Cong., 1st Sess., at 52 (1995).

[46] *See id.*

the FDA through the formal rulemaking process—would create an unacceptable risk of extending the biomaterials supply crisis to the entire field of complex medical devices.

CONCLUSION

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act of 1938 were designed to achieve national uniformity, avoid conflicting state and local rules, and encourage innovation, while preserving tort remedies in appropriate situations approved by the FDA through rulemaking and assuring the continued availability of safe and effective and affordable medical devices. Permitting courts to impose duplicative or even conflicting device requirements, without requiring the State to successfully petition the FDA for an exemption from the preemption provision of the MDA, would violate the letter and spirit of Congress when it enacted the MDA and would introduce serious distortions into the device market that may adversely affect the public health.

Respectfully submitted,

Of Counsel

JAMES LAWSON KIMBLE
AMERICAN INSURANCE ASSOCIATION
1130 Connecticut Avenue, N.W.
Suite 1000
Washington, D.C. 20036
(202) 828-7174

SHERMAN JOYCE
AMERICAN TORT REFORM ASSOCIATION
1212 New York Avenue, N.W.
Suite 515
Washington, D.C. 20005
(202) 682-1163

JAN S. AMUNDSON
NATIONAL ASSOCIATION OF MANUFACTURERS
1331 Pennsylvania Avenue, N.W.
Suite 1500
Washington, D.C. 20004
(202) 637-3055

VICTOR E. SCHWARTZ *
JOSEPH N. ONEK
ROBERT P. CHARROW
MARK A. BEHRENS
MONICA G. PARHAM
CROWELL & MORING
1001 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2595
(202) 624-2500

Attorneys for Amici Curiae

* Counsel of Record